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First Named Inventor:	MARTIN, PHILIP G.		
Application No.:	09/989965	Group Art Unit:	3743
Filed:	November 21, 2001	Examiner:	Joseph F. Weiss Jr.
Title:	FILTERING FACE MASK THAT USES AN EXHALATION VALVE THAT HAS A MULTI-LAYERED FLEXIBLE FLAP		

BRIEF ON APPEAL

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May 10, 2004 — Susan M. Dacko
Date — Signed by: Susan M. Dacko

Dear Sir:

This is an appeal from the Office Action mailed on December 10, 2003. This Brief is being filed in triplicate. The fee required under 37 CFR § 1.17(c) for the appeal should be charged to Deposit Account No. 13-3723.

Appellants request the opportunity for a personal appearance before the Board of Appeals to argue the issues of this appeal. The fee for the personal appearance will be timely paid upon receipt of the Examiner's Answer.

REAL PARTY IN INTEREST

The real party in interest is 3M Company (formerly known as Minnesota Mining and Manufacturing Company) of St. Paul, Minnesota and its affiliate 3M Innovative Properties Company of St. Paul, Minnesota.

RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any related appeals or interferences.

STATUS OF CLAIMS

Claims 1-9, 11-52, and 54-98 are pending in this application and are the subject of this appeal.

STATUS OF AMENDMENTS

An amendment has been filed after the final rejection on January 16, 2004. This amendment was denied entry into the file in an Office Action mailed February 2, 2004.

SUMMARY OF THE INVENTION

Persons who work in polluted environments commonly wear a filtering face mask to protect themselves from inhaling airborne contaminants. Filtering face masks typically have a fibrous or sorbent filter that is capable of removing particulate and/or gaseous contaminants from the air. When wearing a face mask in a contaminated environment, wearers are comforted with the knowledge that their health is being protected, but they are, however, contemporaneously discomforted by the warm, moist, exhaled air that accumulates around their face. The greater this facial discomfort is, the greater the chances are that wearers will remove the mask from their face to alleviate the unpleasant condition.

To reduce the likelihood that a wearer will remove the mask from their face in a contaminated environment, manufacturers of filtering face masks often install an exhalation valve on the mask body to allow the warm, moist, air to be rapidly purged from the mask interior. The rapid removal of the exhaled air makes the mask interior cooler, and, in turn, benefits worker safety because mask wearers are less likely to remove the mask from their face to eliminate the hot moist environment that is located around their nose and mouth.

For many years, commercial respiratory masks have used "button-style" exhalation valves to purge exhaled air from mask interiors. The button-style valves typically have employed a thin circular flexible flap as the dynamic mechanical element that lets exhaled air escape from the mask interior. The flap is centrally mounted to a valve seat through a central post. Examples of button-style valves are shown in U.S. Patents 2,072,516, 2,230,770, 2,895,472, and 4,630,604. When a person exhales, a circumferential portion of the flap is lifted from the valve seat to allow air to escape from the mask interior.

Button-style valves have represented an advance in the attempt to improve wearer comfort, but investigators have made other improvements, an example of which is shown in U.S. Patent 4,934,362 to Braun. The valve described in this patent uses a parabolic valve seat and an elongated flexible flap. Like the button-style valve, the Braun valve also has a centrally-mounted flap and has a flap edge portion that lifts from a seal surface during an exhalation to allow the exhaled air to escape from the mask interior.

After the Braun development, another innovation was made in the exhalation valve art by Japuntich et al. — see U.S. Patents 5,325,892 and 5,509,436. The Japuntich et al. valve uses a single flexible flap that is mounted off-center in cantilevered fashion to minimize the exhalation pressure that is required to open the valve. When the valve-opening pressure is minimized, less power is required to operate the valve, which means that the wearer does not need to work as hard to expel exhaled air from the mask interior when breathing.

Other valves that have been introduced after the Japuntich et al. valve also have used a non-centrally mounted cantilevered flexible flap — see U.S. Patents 5,687,767 and 6,047,698. Valves that have this kind of construction are sometimes referred to as "flapper-style" exhalation valves.

In known valve products, like the exhalation valves described above, the flexible flap has had a monolithic construction. For example, the flexible flap that is described in the '362 patent to Braun is made of pure gum rubber, and the flap that is described in the Japuntich et al. patents is made solely from an elastomeric material such as a crosslinked natural rubber (for example, crosslinked polyisoprene) or a synthetic elastomer such as neoprene, butyl rubber, nitrile rubber, or silicone rubber.

Although known exhalation valve products have been successful at improving wearer comfort by encouraging exhaled air to leave the mask interior, none of the known valve products have used flexible flaps that are made from multiple layers of different material components, which as described below may provide further benefits towards improving valve performance and hence wearer comfort.

The present invention provides a new filtering face mask, which in brief summary, comprises: (a) a mask body that is adapted to fit at least over the nose and mouth of a wearer to create an interior gas space when worn; and (b) an exhalation valve that is in fluid

communication with the interior gas space. The exhalation valve comprises: (i) a valve seat that includes a seal surface and an orifice through which exhaled air may pass to leave the interior gas space; and (ii) a flexible flap that is mounted to the valve seat such that the flap makes contact with the seal surface when the valve is in its closed position and such that the flap can flex away from the seal surface during an exhalation to allow exhaled air to pass through the orifice. The flexible flap includes first and second juxtaposed layers where at least one of the layers is stiffer or has a greater modulus of elasticity than the other layer.

The inventors discovered that the use of a multi-layered flexible flap in a unidirectional fluid valve can provide performance benefits to an exhalation valve for a filtering face mask. In particular, the inventors discovered that a thinner and more dynamic flexible flap may be used in some instances, which can allow the valve to open easier under less pressure drop to enable warm, moist, exhaled air to escape from the mask interior under less exhalation pressure. Wearers therefore may be able to purge larger amounts of exhaled air from the interior gas space more rapidly without expending as much power, resulting in improved comfort to the mask wearer.

The inventors also discovered that a larger process window may be available to manufacturers of the flaps for exhalation valves. When making flapper-style exhalation valves, the thickness and stiffness of the flap material generally needs to be carefully controlled so that the appropriate beam stiffness can be achieved for the flap — otherwise, the valve may be subject to leakage at the point where the flap contacts the valve's seal surface. When making a multi-layered flap of the present invention, however, flap-to-flap variability may not need to be so tightly controlled during the manufacturing process because one layer in the flap can be easily fashioned to provide the flap with its desired beam stiffness. Overall flap thickness tolerances then do not need to be so tightly controlled during manufacture. The structure and benefits of the new exhalation valve may also be applied to an inhalation valve, where the flow through the valve is likewise unidirectional and where improvements in pressure drop across the valve are similarly beneficial to wearer comfort.

ISSUES ON APPEAL

Issue 1

Are claims 57 and 58 indefinite under the terms of 35 USC § 112, second paragraph, because they use the word "preferably?"

Issue 2

Claims 1 and 45 specify that the flexible flap comprises "first and second juxtaposed layers, wherein at least one of the layers is stiffer than the other layer." Is there insufficient antecedent basis for the limitation "the other layer" so as to render the claim indefinite under the terms of 35 USC § 112, second paragraph?

Issue 3

Claims 71-78 recite "the pressure drop" across the valve at a particular flow rate. The term "the pressure drop" is not a positively recited structural feature of the filtering face mask but is a performance feature that is determined in accordance with the test set forth in the paragraph that bridges pages 23 and 24. Is there nonetheless an insufficient antecedent basis for this limitation in claims 71-78 so as to render them indefinite under the terms of 35 USC § 112, second paragraph.

Issue 4

Claims 85-92 cover an exhalation valve that has a valve seat and a flexible flap. U.S. Patent 5,355,910 to Gies et al. (Gies) describes a pressure relief valve for a motor vehicle that has a valve seat and a flap. Does Gies' disclosure of a motor vehicle pressure relief valve anticipate applicants' claims to an exhalation valve?

Issue 5

U.S. Patent 5,325,892 to Japuntich et al. (Japuntich) describes an exhalation valve that has a monolithic flexible flap. Gies, however, discloses a relief valve for a motor vehicle passenger compartment where the flap has multiple layers, which layers include a rigid layer 40 for preventing "warping and flexing of the valve flap." Prevention of warp or flexing is not a

problem that needs to be overcome in the exhalation valve art. Would the combination of Japuntich and Gies have nonetheless rendered the subject matter of claims 1 and 45 obvious to a person of ordinary skill within the meaning of 35 USC § 103?

GROUPING OF CLAIMS

Claims 1, 45, and 95-98 will stand or fall individually. No admission, however, is being made with respect to the obviousness of the subject matter of the other claims.

ARGUMENTS OF APPELLANTS

Issue 1

Because the Amendment mailed January 16, 2004 was not entered into the file, this rejection remains outstanding. The Examiner has applicants' permission to delete the word "preferably" from the claims using an Examiner's amendment. Such an amendment should eliminate this issue

Issue 2

Claims 1 and 45 have been rejected as being indefinite for using of the term "the other layer." The Examiner indicates that there is insufficient antecedent basis for this limitation. Applicants respectfully submit that this rejection cannot be sustained because the antecedent basis for "the other layer" may be found earlier in the claim where it recites the "first and second layers." At least one of these layers is stiffer than the other. When this language is interpreted according to its ordinary or plain meaning, applicants can see no other interpretation that a person of ordinary skill could arrive at. As such, the claim cannot be properly considered to be vague or indefinite under the terms of 35 USC § 112, second paragraph.

Issue 3

Claims 71-78 also have been rejected under 35 USC § 112, second paragraph, because the term "the pressure drop" has no antecedent basis. Applicants respectfully submit that this rejection also cannot be sustained because antecedent basis can be found in the specification in the paragraph that bridges pages 23 and 24. The term "the pressure drop" also is an inferentially

recited performance feature of the filtering face mask. Therefore the claim is properly worded as written. Applicants can see no reason why a person of ordinary skill could not reasonably ascertain the metes and bounds of the claimed subject matter. To eliminate this issue, however, the Examiner is granted permission to amend claims 71-78 in the same as applicants' amended claims 26-35 in the Amendment mailed September 30, 2003.

Issue 4

Claims 85-92 have been rejected under 35 USC § 102(b) for being anticipated by U.S. Patent 5,355,910 to Gies et al. (Gies). This rejection cannot be sustained because Gies does not disclose an exhalation valve. The Examiner maintains the rejection, however, because he ignores the preamble limitation of "an exhalation valve." In so doing, the Examiner cites *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951) as support for his position that no weight should be given to the preamble language.

These cases, however, do not provide any precedential support for the Examiner's position. The former case, *In re Hirao*, only comments on the meaning of the preamble that is used by Hirao et al. in their claim 1. That is, the CCPA only stated what the preamble recited: it did not hold that the preamble language could be ignored. In construing the preamble language, the CCPA found that the preamble limitation was a pertinent part of the claim and that the language furnished the claim with breadth narrower than the Patent Office was attempting to give it:

> The Solicitor points to the preamble of claim 1, which recites a "process for preparing foods and drinks sweetened mildly," as showing that the subject matter as a whole involves the use of an old sweetening agent in a very obvious manner. However, the preamble merely recites the purpose of the process; the remainder of the claim (the three process steps) does not depend on the preamble for completeness, and the process steps are able to stand alone. See Kropa v. Robie, 38 CCPA 858, 187 F.2d 150, 88 USPQ 478 (1951). The Solicitor's interpretation of the preamble would improperly *broaden* the scope of the claim. (emphasis theirs)

Thus, *In re Hirao* certainly does not indicate that the preamble limitation can be ignored. Too the contrary, *In re Hirao* cautions the PTO against not giving the limitation the proper weight, construction, or meaning, which it deserves.

The second case cited by the Examiner also does not support the position taken in the Office Action. In *Kropa v. Robie*, the CCPA found that the preamble term "an abrasive article" was a "vital term" to the claim, which term gave the claim life and meaning and therefore could not be ignored:

> In the case before us, the words "An abrasive article" are essential to point out the invention defined by the counts. In our judgment those introductory words give life and meaning to the counts, for it is only by that phrase that it can be known that the subject matter defined by the claims is comprised as an abrasive article. Every union of substances capable inter alia of use as abrasive grains and a binder is not an "abrasive article." The term calls forth a distinct relationship between the proportions of grain and resin comprising the article. It is important here, as it was in Hall v. Shimadzu, 19 C.C.P.A. (Patents) 1288, 59 F.2d 225, 13 USPQ 259, that the interference counts originated in one party's patent where the entire object of the patent is expressed in the introductory clause of the counts--an objective which nowhere appears in the other party's disclosure (here, appellant's 1938 applications). The term "abrasive article" is a vital term of the counts, and the meaning must be taken from the application in which the counts originated. Kenyon v. Crane, 28 C.C.P.A. (Patents) 1208, 120 F.2d 380, 49 USPQ 707. We hold that it is a limitation which is material to the issue, and must be observed.

Similarly, in the present case, the phrase "an exhalation valve" gives life and meaning to applicants' claim. Not every valve seat and flexible flap is capable of being used as an exhalation valve. The term provides a distinct relationship between these elements such that they would be valuable for use in purging air from the interior of a filtering face mask. In fact, this preamble term, being so distinctly defined in the specification, would never allow the claim to read on a relief valve for a motor vehicle. As the Board is aware, every limitation in a claim is important and must be considered in construing the claim.[1] The Examiner has committed legal error in ignoring claim limitations.[2] The inquiry during examination is patentability of the invention as the applicant regards it.[3] The record unequivocally shows that applicants do not regard "an

[1] *Glaxo Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1566, 42 USPQ2d 1257, 1261 (Fed. Cir. 1997) ("It is elementary patent law that all limitations are material.").
[2] *Id.*
[3] *In re Zletz*, 13 USPQ2d 1320, 1322 ("Thus the inquiry during examination is patentability of the invention as 'the applicants regards' it; and if the claims do not 'particularly point out and distinctly claim', in the words of Section

exhalation valve" to include a relief valve for a motor vehicle. In addition to the cases cited by the Examiner, there are other published decisions that provide precedent for giving the preamble limitation proper weight or consideration.[4] Thus under a proper application of the law, claims 85-92 cannot be properly viewed as being anticipated by Gies.

Issue 5

Claims 1-9, 13-35, 40-52, 56-78, and 83-84 have been rejected under 35 USC § 103 as being unpatentable over U.S. Patent 5,325,892 to Japuntich et al. (Japuntich) in view of Gies. This rejection cannot be properly sustained for a number of important reasons.

Firstly, the record does not contain any evidence for making the Japuntich/Gies combination. In response, the Examiner has stated that Japuntich and Gies can be combined because of "knowledge generally available to one of ordinary skill in the art." The problem with this position, however, is that the Examiner does not identify any such knowledge. The record presently is entirely devoid of any evidence of the so-asserted, generally available knowledge. **Applicants therefore request that the Examiner make the record clear as to what "knowledge" is being using to sustain the rejection. In the absence of such evidence, the rejection must be withdrawn.**[5]

The law is very clear on this point. If there is some general knowledge that exists in the art as to why a person of ordinary skill would have combined the teachings of a relief valve for a passenger compartment with a filtering face mask, the Examiner should, at a minimum, at least explain what that knowledge is.[6] It is entirely improper for the Examiner to state that two distinctly different references may be combined based on a "knowledge generally available to one of ordinary skill" but then never put that knowledge into the record.[7]

112, that which examination shows the applicant is entitled to claim as his invention, the appropriate PTO action is to reject the claims for that reason.").

[4] *See e.g., Rowe v. Dror*, 112 F.3d 473, 479 (Fed. Cir. 1997) (The term "angioplasty" in a preamble reciting a "balloon angioplasty catheter" was considered to be a structural limitation).

[5] *In re Lee*, 61 USPQ2d 1430, 1435 (Fed. Cir. 2002) ("Thus when they rely on what they assert to be general knowledge to negate patentability, that knowledge must be articulated and placed on the record. The failure to do so is not consistent with either effective administrative procedure or effective judicial review.").

[6] *Winner Int'l Royalty Corp. v. Wang*, 53 USPQ2d 1580, 1586-87 (Fed. Cir. 2000) ("[T]he showing of combinability, in whatever form, must nevertheless be 'clear and particular'.").

[7] *See, Lee*, 61 USPQ2d at 1435; *see also In re Peehs*, 204 USPQ 835, 837 (CCPA 1980) ("[I]t is incumbent upon the PTO to explain its reasons if it disagrees. A mere conclusory statement...is inadequate.").

In an earlier Office Action, the Examiner held that Japuntich and Gies would be combinable because "[t]he suggestion/motivation for doing so would have been to provide for a more effective valve operation to achieve the objects of the invention contemplated by Japuntich (see Summary of the invention) which Gies stipulates such types of operable features are in accord with and more effectively/reliably obtainable via his reed valve structure (summary of invention, note recitations of enhanced seal characteristics, control of flow and operation of the valve)." The problem with this earlier position is that Gies does not address any of the objects contemplated by Japuntich.

The Japuntich valve was designed to maintain a seal under any orientation of the valve, while providing minimal pressure drop during an exhalation. Gies is not concerned with producing a valve that remains closed under any orientation. Gies uses his valve on a motor vehicle for pressure relief purposes. Passenger compartment valves have no need to remain closed under any orientation. In addition, Gies does not address any need for a valve that can open under minimal exhalation pressure. The force exerted by slamming a motor vehicle door is certainly magnitudes larger than the force exerted by a person's exhalation breath. Thus, the Examiner's asserted reason for making the combination is wrong; the record, as it presently stands, therefore fails to contain any evidence of a teaching, suggestion, or motivation to combine Japuntich and Gies.

In view of the above, the only remaining basis for combining Japuntich with Gies appears to be the alleged "general knowledge" that persons of ordinary skill possess. As indicated above, however, the record, must be made clear as to what this knowledge is, or the rejection must be withdrawn. As the Federal Circuit said in *W.L. Gore*, **"[t]o imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher."**[8] A vague reference to common knowledge and common sense is <u>not</u> a substitute for evidence.[9] If the Examiner is still relying on his earlier position that Gies addresses the objects of Japuntich (despite no apparent need for these objects in a motor vehicle pressure relief valve

[8] *W.L. Gore v. Garlock Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983) (emphasis added).

or vice versa) this too should be made clear. In short, the record must contain some *evidence* of a suggestion to combine the teachings of these two manifestly different references.[10] Mere opinions or bald conclusions do not suffice.[11] An invention is not obvious without a suggestion to make the modification.[12]

Secondly, it is not proper to view the applicants' invention in retrospect, once having learned of their discovery. Applicants' specification is the only document that teaches the use of a multi-layered flap in an exhalation valve. Applicants' specification also is the only document that explains the benefits of using such a valve on a filtering face mask. The inventors discovered that a thinner and more dynamic flexible flap may be used in some instances, which can allow the valve to open easier under less pressure drop to enable warm, moist, exhaled air to escape from the mask interior under less exhalation pressure. Wearers therefore may be able to purge larger amounts of exhaled air from the interior gas space more rapidly without expending as much power, resulting in improved comfort to the mask wearer. The inventors also discovered that a larger process window may be available to manufacturers of the flaps for exhalation valves. When making flapper-style exhalation valves, the thickness and stiffness of the flap material generally needs to be carefully controlled so that the appropriate beam stiffness can be achieved for the flap — otherwise, the valve may be subject to leakage at the point where the flap contacts the valve's seal surface. When making a multi-layered flap of the present invention, however, flap-to-flap variability may not need to be so tightly controlled during the manufacturing process because one layer in the flap can be easily fashioned to provide the flap with its desired beam stiffness. Overall flap thickness tolerances then do not need to be so tightly controlled during manufacture. The structure and benefits of the new exhalation valve may also be applied to an inhalation valve, where the flow through the valve is likewise unidirectional and where improvements in pressure drop across the

[9] *In re Lee*, 61 USPQ2d 1430, 1435 (Fed. Cir. 2002) ("'Common knowledge and common sense,' even if assumed to derive from the agency's expertise, do not substitute for authority when the law requires authority.").
[10] *In re Fritch*, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992) ("The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. Wilson and Hendrix fail to suggest any motivation for, or desirability of, the changes espoused by the Examiner and endorsed by the Board.").
[11] *See, Lee*, 61 USPQ2d at 434 ("The examiner's conclusory statements that 'the demonstration mode is just a programmable feature which can be used in many different devices[s] for providing automatic introduction by adding the proper programming software' and that 'another motivation would be that the automatic demonstration mode is user friendly and it functions as a tutorial' do not adequately address the issue of motivation to combine. This factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority.").
[12] *In re Lakowski*, 10 USPQ2d 1397, 1399 (Fed. Cir. 1989).

valve are similarly beneficial to wearer comfort. These new teachings provide very good evidence of nonobviousness.[13] The prior art does not teach or suggest what applicants have done; nor does it appreciate the benefits that the multi-layered flap provides.

When none of these benefits and structural differences are appreciated by the prior art, they could only be arrived at through a hindsight reconstruction of the invention, which, of course, is inappropriate under the terms of 35 USC § 103..

Thirdly, Gies is not an analogous reference and therefore cannot be applied in making a § 103 rejection. To show that a reference is analogous, the Examiner must establish that the reference is in applicants' field of endeavor or is reasonably pertinent to the problem with which the applicant was concerned.[14] The Examiner indicates that Gies resides in the respiratory arts and therefore is in applicants' field of endeavor. If this is the only basis that the Examiner is using for holding that Gies is an analogous reference, applicants respectfully assert that the Examiner has committed legal error by painting with a very broad brush in defining the field of endeavors for which the applicants' invention and the Gies patent reside.

The Examiner attempts to assert a common field by broadly casting both applicants' field and Gies' field as both being in the "respiratory arts". The field "respiratory arts" could include many things unrelated to filtering face masks, such as medical devices or drug delivery systems that are used to improve breathing in, for example, patients with asthma or emphysema. But even if the test for determining whether a reference was analogous merely depended on whether the English language could be used to craft some overlapping commonality amongst different arts, the attempt to do here would nonetheless fail because a pressure relief valve for a motor vehicle has nothing to do with "respiration" or the "respiratory arts."

Applicants' invention pertains to a filtering face mask that uses an exhalation valve. An exhalation valve operates under the cadence of a persons' breathing rate, and the valve desirably remains seated or closed under any orientation of the mask and yet is able to open under minimal exhalation pressure when a wearer exhales. The goal of applicants' invention is to purge larger amounts of exhaled air from the mask interior, more rapidly, without expending as much power,

[13] *In re Saether*, 181 USPQ 36, 40 (CCPA 1974) ("In addition to the differences from the prior art, which is shown by the references and by appellant's specification, further evidence of unobviousness is shown by the improvements and unexpected results obtained by the claimed invention.").
[14] *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).

which achievements result in improved comfort to the mask wearer. The field of filtering face masks for exhalation valves is a far cry from the field of automobile passenger compartment relief valves, which only operate when a person slams shut a motor vehicle door.

In the Examiner's Answer, it would be helpful if the Examiner could elaborate on how Gies allegedly resides in the "respiratory arts", if this rejection is intended to be maintained on this basis. It would also be helpful if the Examiner could explain why the broadly cast field of "respiratory arts" is being used, as opposed to the field of "filtering face masks". If the Examiner also takes the position that Gies is also analogous because it provides a disclosure that is "reasonably pertinent to the problem of which the applicant was concerned", applicants respectfully ask that the Examiner make the record clear as to what "particular problem with which the applicant was concerned" that is also addressed by Gies. Although the Examiner, in the Office Action mailed December 10, 2003 (page 19) also "bolded" the second portion of the two-part test for determining whether a reference is analogous, no cogent reasoning or explanation has yet been provided to set forth the "particular problem with which the applicant was concerned."

When the cited reference resides in a different field of endeavor, the Examiner still needs to evaluate whether the cited reference is reasonably pertinent to the particular problem that confronted the inventor. In making this evaluation, the Examiner must compare the purpose(s) of the invention with purpose(s) of the prior art. When the prior art disclosure is directed to a different purpose than the claimed invention, the reviewing courts have held that the reference resides in a nonanalogous art. The Board's attention is directed to *In re Clay*, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992) where the Federal Circuit stated that the purpose of the cited technology needs to be compared to the purpose of the claimed invention:

> A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. **Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve.** If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his intention. **If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it** (emphasis added).

Applicants' valve has the purpose of providing a low pressure drop valve that remains closed under neutral conditions; whereas Gies' valve has the purpose of relieving pressure from the interior of a motor vehicle compartment. Further, applicants' valve operates in accordance with the cadence of a person's breathing while the Gies valve only operates when the door to the passenger compartment is closed.[15] In view of the different fields of endeavor, the different problems that mask designs tackle over the problems confronted by designers of motor vehicle relief valves, and the different purposes and conditions under which these valves operate, Gies cannot reside in an art analogous to applicants' invention.

Finally, the Gies valve is not designed to address the features of the applicants' invention. As such, Gies contributes little or nothing to the asserted obviousness of applicants' invention. The Gies valve relies on gravity to keep its valve closed. This valve would not be suitable for use in an exhalation valve because the flap would easily open when a wearer tilted their head downwards. A quick review of the Gies patent reveals that the rigid layer is isolated from the hinge — that is, it is not part of the hinge: it does not bend or flex when the valve opens. The rigid layer in Gies is only employed to prevent warping or deformation of the flap 22. As such there is no apparent prestress on the Gies flap; its valve therefore could allow contaminants to enter a face mask interior, if it were to be used for such a purpose. The Examiner indicated that the open-ended claim language used in applicants' claims, precludes the Examiner from giving any weight to the arguments regarding the effect of gravity on applicants' valve. As the Board surely understands, the claims are used only to define the metes and bounds of the subject matter being claimed. The

[15] *In re Clay* also indicates that the operating conditions, under which the invention and prior art operate, should also be evaluated and when those conditions are different, it supports a finding that the reference is not analogous.

"Remarks" section in an Amendment or Response is what is used to present arguments. The arguments do not also need to be set forth in the claim in order for them to be considered. There also is no need to recite the advantages in a claim for them to be considered.[16] The advantages and properties of an invention must be considered, regardless of being recited in the claim. The "invention as a whole" requirement set forth in 35 USC § 103 demands that all aspects of an invention be considered in evaluating obviousness under 35 USC § 103.[17]

Claims 95-98

The subject matter of these claims also is nonobvious over Japuntich and Gies for the reasons presented above with respect to claims 1 and 45. Claims 95 and 96 are further patentable in that they recite a flexible flap that has first and second layers in the region where the flap bends when the flap flexes away from the seal surface during an exhalation. Claims 97 and 98 define additionally patentable subject in that they require that the stiffer layer be disposed on the flap in the region where the flap bends when the flap flexes away from the seal surface during an exhalation.

A review of the Gies patent shows a gap 42 that is created by the absence of the second strip 40. The second strip 40 has a rigid plastic material that is provided to prevent warping of the flap. The gap 42 is provided to permit the sheet 24 to flex along the line defined by the gap. The gap 42 thus serves "as an integral living hinge to allow the necessary relative pivoting movement between the strip 40 and the mounting strip 34."[18]

Because Gies does not teach or suggest first and second layers on a flap "in the region where the flap bends" or does not teach or suggest the provision of a stiffer layer on the flap "in the region where the flap bends", Gies does not suggest the subject matter of claims 95-98. Because Japuntich does not teach or suggest a multi-layered flap, Japuntich also does not teach or suggest these features of the present invention. As such, claims 95-98 are patentable for this additional reason.

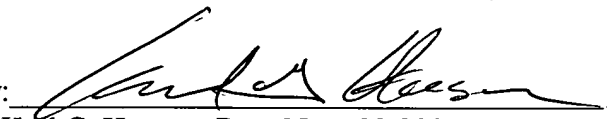
[16] *In re Estes*, 164 USPQ 519, 521 (CCPA 1970) ("There can be no doubt from the record that these advantages accrue from the claimed process, it is not required that they be recited [in the claims].").
[17] *In re Papesch*, 137 USPQ 43 (CCPA 1963); *In re von Schickh*, 150 USPQ 300, 302 (CCPA 1966).
[18] *Gies* at column 4, lines 8-14.

CONCLUSION

For the foregoing reasons, appellants respectfully submit that the Examiner has erred in rejecting this application under 35 USC §§ 112, 102, and 103. Please reverse the decision below.

Respectfully submitted,

May 10, 2004
Date

By: 
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APPENDIX

1. A filtering face mask that comprises:

(a) a mask body that is adapted to fit at least over the nose and mouth of a wearer to create an interior gas space when worn; and

(b) an exhalation valve that is in fluid communication with the interior gas space, the exhalation valve comprising:

(i) a valve seat that comprises a seal surface and an orifice through which exhaled air may pass to leave the interior gas space; and

(ii) a flexible flap that is mounted to the valve seat such that the flap makes contact with the seal surface when the valve is in a closed position and such that the flap can flex away from the seal surface during an exhalation to allow exhaled air to pass through the orifice to ultimately enter an exterior gas space, the flexible flap comprising at least first and second juxtaposed layers, wherein at least one of the first and second layers is stiffer than the other layer.

2. The filtering face mask of claim 1, wherein the first and second layers comprise first and second materials, respectively, that each have a different modulus of elasticity.

3. The filtering face mask of claim 2, wherein the first layer is disposed closer to the seal surface than the second layer when the flap is positioned against the seal surface, and wherein the second layer has a greater modulus of elasticity than the first layer.

4. The filtering face mask of claim 3, wherein the first layer contacts the seal surface when the flap is positioned against the seal surface.

5. The filtering face mask of claim 1, wherein the exhalation valve is mounted to the mask body.

6. The filtering face mask of claim 1, which is a negative pressure half-mask that has a fluid-permeable mask body that contains a layer of filter material.

7. The filtering face mask of claim 1, wherein the exhalation valve is a flapper-style exhalation valve.

8. The filtering face mask of claim 7, wherein the flapper-style exhalation valve has a planar seal surface.

9. The filtering face mask of claim 8, wherein the flexible flap is not pressed against the seal surface under neutral conditions.

11. The filtering face mask of claim 1, wherein the flexible flap includes a third layer that has substantially the same stiffness as the first layer.

12. The filtering face mask of claim 11, wherein the flexible flap exhibits symmetry with respect to the second layer, and wherein the second layer is stiffer than the first and third layers.

13. The filtering face mask of claim 1, wherein the second layer has a modulus of elasticity that is greater than the first layer, and wherein the first layer contacts the seal surface when the flap is positioned against the seal surface.

14. The filtering face mask of claim 13, wherein the modulus of elasticity of the first layer is about 0.15 to 10 megaPascals, and wherein the modulus of elasticity of the second layer is about 2 to 1.1 x 10^6 megaPascals.

15. The filtering face mask of claim 13, wherein the modulus of elasticity of the first layer is preferably about 1 to 7 megaPascals, and wherein the modulus of elasticity of the second layer is about 200 to 11,000 megaPascals.

16. The filtering face mask of claim 15, wherein the second layer has a modulus of elasticity of 300 to 5000 megaPascals.

17. The filtering face mask of claim 1, wherein the second layer is stiffer than the first layer, and wherein the moduli ratio between the first layer and the second layer is less than 1.

18. The filtering face mask of claim 1, wherein the second layer is stiffer than the first layer, and wherein the moduli ratio between the first layer and the second layer is less than 0.01.

19. The filtering face mask of claim 1, wherein the second layer is stiffer than the first layer, and wherein the moduli ratio between the first layer and the second layer is less than 0.001.

20. The filtering face mask of claim 3, wherein the flexible flap has a thickness of about 10 to 2,000 μm.

21. The filtering face mask of claim 3, wherein the flexible flap has a thickness of about 20 to 700 μm.

22. The filtering face mask of claim 3, wherein the flexible flap has a thickness of about 25 to 600 μm.

23. The filtering face mask of claim 3, wherein the first layer has a thickness of about 5 to 700 μm, and wherein the second layer has a thickness of about 5 to 100 μm.

24. The filtering face mask of claim 3, wherein the first layer has a thickness of about 10 to 600 μm, and wherein the second layer has a thickness of about 10 to 85 μm.

25. The filtering face mask of claim 3, wherein the first layer has a thickness of about 12 to 500 μm, and wherein the second layer has a thickness of about 15 to 75 μm.

26. The filtering face mask of claim 3, wherein a pressure drop across the valve at a flow rate of 85 liters per minute is less than about 50 Pascals.

27. The filtering face mask of claim 3, wherein a pressure drop across the valve at a flow rate of 85 liters per minute is less than about 40 Pascals.

28. The filtering face mask of claim 3, wherein a pressure drop across the valve at a flow rate of 85 liters per minute is less than about 30 Pascals.

29. The filtering face mask of claim 3, wherein a pressure drop across the valve at a flow rate of 10 liters per minute is less than 30 Pascals.

30. The filtering face mask of claim 3, wherein a pressure drop across the valve at a flow rate of 10 liters per minute is less than 30 Pascals.

31. The filtering face mask of claim 3, wherein a pressure drop across the valve at a flow rate of 10 liters per minute is less than 25 Pascals.

32. The filtering face mask of claim 3, wherein a pressure drop across the valve at a flow rate of 10 liters per minute is less than 20 Pascals.

33. The filtering face mask of claim 3, wherein a pressure drop across the valve is about 5 to 50 Pascals between flow rates of 10 liters per minute and 85 liters per minute.

34. The filtering face mask of claim 3, wherein a pressure drop across the valve is about 5 to 25 Pascals between flow rates of 10 liters per minute and 85 liters per minute.

35. The filtering face mask of claim 9 wherein a pressure drop is less than 5 Pascals at flow rates of 10 liters per minute.

36. The filtering face mask of claim 1, wherein the exhalation valve includes a third layer such that the flap has an ABA construction, wherein the B layer is stiffer than the A layers.

37. The filtering face mask of claim 1, wherein the exhalation valve includes a third layer such that the flap has an ABA' construction, wherein the B layer is stiffer than the A and A' layers, and wherein the A layer is located closer to the seal surface than the B layer.

38. The filtering face mask of claim 1, wherein the exhalation valve includes a third layer such that the flap has an ABC construction, wherein the B layer is stiffer than the A layers, and wherein the A layer is located closer to the seal surface than the B layer.

39. The filtering face mask of claim 1, wherein the exhalation valve includes a third layer such that the flap has an ABC construction, wherein the C layer is stiffer than the A and B layers, and is located closer to the seal surface than the A and B layers.

40. The filtering face mask of claim 1, wherein the first and second layers both contain polymer materials.

41. The filtering face mask of claim 3, wherein the first layer contains a rubber, and wherein the second layer contains polyethylene terephthalate or polycarbonate.

42. The filtering face mask of claim 41, wherein rubber is a styrene-butadiene-styrene block copolymer.

43. The filtering face mask of claim 1, wherein the exhalation valve exhibits a valve efficiency of about 2 to 20 mW•g cm^3/min.

44. The filtering face mask of claim 1, wherein the exhalation valve exhibits a valve efficiency of about 2 to 10 mW•g cm^3/min.

45. A filtering face mask that comprises:

(a) a mask body that is adapted to fit at least over the nose and mouth of a wearer to create an interior gas space when worn; and

(b) an exhalation valve that is in fluid communication with the interior gas space, the exhalation valve comprising:

(i) a valve seat that comprises a seal surface and an orifice through which exhaled air may pass to leave the interior gas space; and

(ii) a flexible flap that is mounted to the valve seat such that the flap makes contact with the seal surface when the valve is in a closed position and such that the flap can flex away from the seal surface during an exhalation to allow exhaled air to pass through the orifice to ultimately enter an exterior gas space, the flexible flap comprising at least first and second juxtaposed layers, wherein at least one of the layers has a greater modulus of elasticity than the other layer.

46. The filtering face mask of claim 40, wherein the first layer is disposed closer to the seal surface than the second layer when the flap is positioned against the seal surface, and wherein the second layer has a greater modulus of elasticity than the first layer.

47. The filtering face mask of claim 46, wherein the first layer contacts the seal surface when the flap is positioned against the seal surface.

48. The filtering face mask of claim 45, wherein the exhalation valve is mounted to the mask body.

49. The filtering face mask of claim 48, which is a negative pressure half-mask that has a fluid-permeable mask body that contains a layer of filter material.

50. The filtering face mask of claim 45, wherein the exhalation valve is a flapper-style exhalation valve.

51. The filtering face mask of claim 50, wherein the flapper-style exhalation valve has a planar seal surface.

52. The filtering face mask of claim 50, wherein the flexible flap is not pressed against the seal surface under neutral conditions.

54. The filtering face mask of claim 45, wherein the flexible flap includes a third layer that has substantially the same modulus of elasticity as the first layer.

55. The filtering face mask of claim 54, wherein the flexible flap exhibits symmetry with respect to the second layer, and wherein the second layer is stiffer than the first and third layers.

56. The filtering face mask of claim 45, wherein the second layer has a modulus of elasticity that is greater than the first layer, and wherein the first layer contacts the seal surface when the flap is positioned against the seal surface.

57. The filtering face mask of claim 56, wherein the modulus of elasticity of the first layer is preferably about 0.15 to 10 megaPascals, and wherein the modulus of elasticity of the second layer is about 2 to 1.1×10^6 megaPascals.

58. The filtering face mask of claim 56, wherein the modulus of elasticity of the first layer is preferably about 2 to 5 megaPascals, and wherein the modulus of elasticity of the second layer is about 200 to 11,000 megaPascals.

59. The filtering face mask of claim 58, wherein the second layer has a modulus of elasticity of 300 to 500 megaPascals.

60. The filtering face mask of claim 45, wherein the second layer has a greater modulus of elasticity than the first layer, and wherein the moduli ratio between the first layer and the second layer is less than 1.

61. The filtering face mask of claim 45, wherein the second layer has a greater modulus of elasticity than the first layer, and wherein the moduli ratio between the first layer and the second layer is less than 0.01.

62. The filtering face mask of claim 45, wherein the second layer has a greater modulus of elasticity than the first layer, and wherein the moduli ratio between the first layer and the second layer is less than 0.001.

63. The filtering face mask of claim 46, wherein the flexible flap has a thickness of about 10 to 2,000 μm.

64. The filtering face mask of claim 46, wherein the flexible flap has a thickness of about 20 to 700 μm.

65. The filtering face mask of claim 46, wherein the flexible flap has a thickness of about 25 to 600 μm.

66. The filtering face mask of claim 46, wherein the first layer has a thickness of about 5 to 700 μm, and wherein the second layer has a thickness of about 5 to 100 μm.

67. The filtering face mask of claim 46, wherein the first layer has a thickness of about 10 to 600 μm, and wherein the second layer has a thickness of about 10 to 85 μm.

68. The filtering face mask of claim 46, wherein the first layer has a thickness of about 12 to 500 μm, and wherein the second layer has a thickness of about 15 to 75 μm.

69. The filtering face mask of claim 46, wherein a pressure drop across the valve at a flow rate of 85 liters per minute is less than about 50 Pascals.

70. The filtering face mask of claim 46, wherein a pressure drop across the valve at a flow rate of 85 liters per minute is less than about 40 Pascals.

71. The filtering face mask of claim 46, wherein the pressure drop across the valve at a flow rate of 85 liters per minute is less than about 30 Pascals.

72. The filtering face mask of claim 46, wherein the pressure drop across the valve had a flow rate of 10 liters per minute is less than 30 Pascals.

73. The filtering face mask of claim 46, wherein the pressure drop across the valve had a flow rate of 10 liters per minute is less than 30 Pascals.

74. The filtering face mask of claim 46, wherein the pressure drop across the valve had a flow rate of 10 liters per minute is less than 25 Pascals.

75. The filtering face mask of claim 46, wherein the pressure drop across the valve had a flow rate of 10 liters per minute is less than 20 Pascals.

76. The filtering face mask of claim 46, wherein the pressure drop across the valve is about 5 to 50 Pascals between flow rates of 10 liters per minute and 85 liters per minute.

77. The filtering face mask of claim 46, wherein the pressure drop across the valve is about 5 to 25 Pascals between flow rates of 10 liters per minute and 85 liters per minute.

78. The filtering face mask of claim 51 wherein the pressure drop is less than 5 Pascals at flow rates of 10 liters per minute.

79. The filtering face mask of claim 45, wherein the exhalation valve includes a third layer such that the flap has an ABA construction, wherein the B layer is stiffer than the A layers.

80. The filtering face mask of claim 45, wherein the exhalation valve includes a third layer such that the flap has an ABA' construction, wherein the B layer is stiffer than the A layers, and wherein the A layer is located closer to the seal surface than the B layer.

81. The filtering face mask of claim 45, wherein the exhalation valve includes a third layer such that the flap has an ABC construction, wherein the B layer is stiffer than the A layers, and wherein the A layer is located closer to the seal surface than the B layer.

82. The filtering face mask of claim 45, wherein the exhalation valve includes a third layer such that the flap has an ABC construction, wherein the C layer is stiffer than the A and B layers, and is located closer to the seal surface than the A and B layers.

83. The filtering face mask of claim 45, wherein the exhalation valve exhibits a valve efficiency of about 2 to 20 mW•g cm^3/min.

84. The filtering face mask of claim 45, wherein the exhalation valve exhibits a valve efficiency of about 2 to 0 mW•g cm^3/min.

85. An exhalation valve that comprises:

(i) valve seat that comprises a seal surface and an orifice through which a fluid may pass; and

(ii) a flexible flap that is mounted to the valve seat such that the flap makes contact with the seal surface when the valve is in its closed position and such that the flap can flex away from the seal surface when an exhale flow stream is passing through the valve, the flexible flap comprising at least first and second juxtaposed layers, wherein at least one of the layers is stiffer than the other layer.

86. The exhalation valve of claim 85, wherein the first layer is disposed closer to the seal surface than the second layer when the valve is closed, and wherein the second layer is stiffer than the first layer.

87. An exhalation valve that comprises:

(i) valve seat that comprises a seal surface and an orifice through which a fluid may pass; and

(ii) a flexible flap that is mounted to the valve seat such that the flap makes contact with the seal surface when the valve is in its closed position and such that the flap can flex away from the seal surface when an exhale flow stream is passing through the valve, the flexible flap comprising at least first and second juxtaposed layers, wherein at least one of the layers has a greater modulus of elasticity than the other layer.

88. The exhalation valve of claim 87, wherein the first layer is disposed closer to the seal surface than the second layer when the valve is closed, and wherein the second layer has a greater modulus of elasticity than the first layer.

89. An inhalation valve that comprises:

(i) valve seat that comprises a seal surface and an orifice through which a fluid may pass; and

(ii) a flexible flap that is mounted to the valve seat such that the flap makes contact with the seal surface when the valve is in its closed position and such that the flap can flex away from the seal surface when an inhale flow stream is passing through the valve, the flexible flap comprising at least first and second juxtaposed layers, wherein at least one of the layers is stiffer than the other layer.

90. The inhalation valve of claim 89, wherein the first layer is disposed closer to the seal surface than the second layer when the valve is closed, and wherein the second layer is stiffer than the first layer.

91. An inhalation valve that comprises:

(i) valve seat that comprises a seal surface and an orifice through which a fluid may pass; and

(ii) a flexible flap that is mounted to the valve seat such that the flap makes contact with the seal surface when the valve is in its closed position and such that the flap can flex away from the seal surface when an inhale flow stream is passing through the valve, the flexible flap comprising at least first and second juxtaposed layers, wherein at least one of the layers has a greater modulus of elasticity than the other layer.

92. The inhalation valve of claim 91, wherein the first layer is disposed closer to the seal surface than the second layer when the valve is closed, and wherein the second layer has a greater modulus of elasticity than the first layer.

93. A filtering face mask that comprises the inhalation valve of claim 89.

94. A filtering face mask that comprises the inhalation valve of claim 91.

95. The filtering face mask of claim 1, wherein the first and second juxtaposed layers are both disposed on the flexible flap in the region where the flap bends when the flap flexes away from the seal surface during an exhalation.

96. The filtering face mask of claim 45, wherein the first and second juxtaposed layers are both disposed on the flexible flap in the region where the flap bends when the flap flexes away from the seal surface during an exhalation.

97. The filtering face mask of claim 1, wherein the stiffer layer is disposed on the flap in the region where the flap bends when the flap flexes away from the seal surface during exhalation.

98. The filtering face mask of claim 45, wherein the stiffer layer is disposed on the flap in the region where the flap bends when the flap flexes away from the seal surface during exhalation.